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[Canada.ca](#) > [Departments and agencies](#) > [Health Canada](#)

> [Drugs and health products](#) > [Drug products](#) > [Fact Sheets – Drug products](#)

How Drugs are Reviewed in Canada

Contact: [Office of Submissions and Intellectual Property \(OSIP\)](#).

How are drugs reviewed in Canada?

Drugs are authorized for sale in Canada once they have successfully gone through the drug review process. This process is the means by which a drug application is reviewed by scientists in the Health Products and Food Branch (HPFB) of Health Canada, and on occasion, outside experts, to assess the safety, efficacy and quality of a drug.

Throughout the process, the safety and well-being of Canadians is the paramount concern.

Quick Links

- [Food and Drugs Act Liaison Office](#)

What is the Health Products and Food Branch?

Health Canada's HPFB is the national authority that regulates, evaluates and monitors the safety, efficacy, and quality of therapeutic and diagnostic products available to Canadians. These products include drugs, medical

devices, disinfectants and sanitizers with disinfectant claims.

What is considered to be a drug?

Drugs include both prescription and nonprescription pharmaceuticals; biologically-derived products such as vaccines, blood derived products, and products produced through biotechnology; tissues and organs; disinfectants; and radiopharmaceuticals. According to the *Food and Drugs Act*, "a drug includes any substance or mixture of substances manufactured, sold or represented for use in:

- a. the diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in human beings or animals;
- b. restoring, correcting or modifying organic functions in human beings or animals; or
- c. disinfection in premises in which food is manufactured, prepared or kept."

Natural health products, such as vitamin and mineral supplements and herbal products for which therapeutic claims are made are also considered drugs at the level of the *Food and Drugs Act*; however, these products are regulated as natural health products under the *Natural Health Products Regulations* and not as drugs under the *Food and Drug Regulations*.

How are drugs developed?

Research for new drugs begins with scientists developing various chemical or biological substances. Once a substance has been isolated and purified, it is administered to tissue cultures or to a variety of small animals to see

whether or not there are significant changes. These changes may be biochemical, physiological or behavioural in nature.

If promising results are obtained from these initial studies, a variety of animal and laboratory tests are conducted to study other effects of the substance [for example (e.g.) how it affects the immune system or reproductive system] and to determine what dosage of the substance should be given to achieve a particular effect.

If these preclinical tests indicate that a substance produces the desired result and is not toxic, the sponsor [that is (i.e.) the person or company who takes responsibility for the application] may apply to HPFB for authorization to conduct a clinical trial in Canada.

What is the intent of a clinical trial?

The intent of a clinical trial is to research and gather information on a drug's dose, effectiveness and safety in humans. Trials are undertaken with informed and consenting human subjects according to good clinical practices. This provides a controlled environment where the procedures for drug administration and the evaluation of the results are closely monitored.

Does HPFB review clinical trials?

Prior to the commencement of a clinical trial in Canada, HPFB reviews the information submitted in the clinical trial application. This application requests permission to distribute the drug to responsible clinical investigators that are named in the application. Some of the information

contained in a clinical trial application includes the results from preclinical tests, production methods, dosage form and information regarding the investigators who will be conducting the study.

What is done with the results from clinical trials?

If clinical trial studies prove that the drug has potential therapeutic value that outweighs the risks associated with its use (e.g. adverse effects, toxicity), the sponsor may choose to file a New Drug Submission with HPFB.

What are the steps in the review process for a drug?

1. When a sponsor decides that it would like to market a drug in Canada, it files a "New Drug Submission" with HPFB. This contains information and data about the drug's safety, effectiveness and quality. It includes the results of the preclinical and clinical studies, whether done in Canada or elsewhere, details regarding the production of the drug, packaging and labelling details, and information regarding therapeutic claims and side effects.
2. HPFB performs a thorough review of the submitted information, sometimes using external consultants and advisory committees.
3. HPFB evaluates the safety, efficacy and quality data to assess the potential benefits and risks of the drug.
4. HPFB reviews the information that the sponsor proposes to provide to health care practitioners and consumers about the drug (e.g. the label, product brochure).

5. If, at the completion of the review, the conclusion is that the benefits outweigh the risks and that the risks can be mitigated, the drug is issued a Notice of Compliance (NOC), as well as a Drug Identification Number (DIN) which permits the sponsor to market the drug in Canada and indicates the drug's official approval in Canada.
6. In addition, Health Canada laboratories may test certain biological products before and after authorization to sell in Canada has been issued. This is done through its Lot Release Process, in order to monitor safety, efficacy and quality.

Why are some drugs not approved?

If there is insufficient evidence to support the safety, efficacy or quality claims, HPFB will not grant a marketing authorization for the drug. All drugs granted marketing authorization in Canada are reviewed to ensure that they meet the requirements of the *Food and Drugs Act*.

What happens when a drug is not approved?

If HPFB decides not to grant a marketing authorization, the sponsor has the opportunity to supply additional information, to re-submit its submission at a later date with additional supporting data, or to ask that HPFB reconsider its decision.

How long does the drug review process take?

HPFB has set internationally competitive performance targets for its conduct of reviews. The length of time for review depends on the product being submitted and the size and quality of the submission, and is

influenced by HPFB's workload and human resources.

Are some drugs reviewed more quickly?

HPFB has a Priority Review Process in place which allows for a faster review to make available promising drug products for life-threatening or severely debilitating conditions, such as cancer, AIDS, or Parkinson's Disease, for which there are few effective therapies already on the market.

How does Health Canada use Monographs during the review process?

A monograph is a scientific standard. It contains information about an ingredient, product or class of products: its properties; acceptable use or purpose; dosage; duration of use; risk information; etc. The monograph represents Health Canada's knowledge and experience about what is necessary for the safe and effective use of the ingredient, product, or class of products.

Monographs have been developed for many natural health products and some non-prescription and disinfectant drugs. If an applicant wants to market a product that follows a monograph exactly, the process to obtain approval will be faster because Health Canada has already pre-cleared the information.

The Natural and Non-prescription Health Products Directorate's (NNHPD) product licensing system allows applicants to reference monographs for certain non-prescription drugs to support the safety and efficacy of these products, allowing for an expedited review of the Licence/DIN application.

Can important therapies or drugs be obtained prior to market authorization in Canada?

The Special Access Program, administered by HPFB, allows physicians to gain access to drugs which are not currently available in Canada. Following approval by the Special Access Programme, a physician may prescribe such a drug to specified patients, if it is the physician's belief that conventional therapies have failed or are inappropriate. The drug is only released after HPFB has determined that the need is legitimate and that a qualified physician is involved. The drug's manufacturer must also agree to release the product to the qualified physician.

Once a drug has been approved, how is it monitored?

Once a drug is on the market, regulatory controls continue. The distributor of the drug must report any new information received concerning serious side effects including failure of the drug to produce the desired effect. The distributor must also notify HPFB about any studies that have provided new safety information and request approval for any major changes to the manufacturing processes, dose regime or recommended uses for the drug.

HPFB conducts market surveillance, monitors adverse reaction reports, investigates complaints and problem reports, and manages recalls, should the necessity arise.

In addition, HPFB licenses most drug production sites and conducts regular inspections as a condition for licensing.

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